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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

DATE: January 21, 2010

SUBJECT: Science Review in Support of the Registration of SummerSet All Down Herbicide® Containing 8.00% Acetic Acid and 6.00% Citric Acid As Its Active Ingredients.

Decision Number: 389083
DP Number: 366445
EPA File Symbol Number: 84069-R
Chemical Class: Biochemicals
PC Code: 044001 (acetic acid), 021801 (citric acid)
CAS Number: 64-19-7 (acetic acid), 77-92-9 (citric acid)
Active Ingredient Tolerance Exemptions: tolerance pending (acetic acid), 180.950 (citric acid)
MRID Numbers: 47330501 through 47330518, 47775901

FROM: Angela L. Gonzales, Biologist 01/21/10
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Cheryl Greene, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

In response to the request for additional information discussed in a memorandum from A. L. Gonzales to C. Greene dated April 10, 2009 and relayed in a letter to the registrant dated June 3, 2009, the registrant has submitted a revised proposed label, a revised Confidential Statement of Formula (CSF) dated June 10, 2009, product chemistry data in MRID 47775901 and additional information and data in the cover letter dated June 11, 2009 and associated materials. MRIDs 47330501 through 47330518 were submitted in the original data package and are discussed in this memorandum.

RECOMMENDATIONS AND CONCLUSIONS

Note: A tolerance exemption is pending for acetic acid.

1. The product chemistry submission is ACCEPTABLE.
MRID 47775901: ACCEPTABLE

Regarding the EP:

a. All previously identified deficiencies have been resolved.

Regarding Acetic Acid:

a. All previously identified deficiencies have been resolved.

Regarding Citric Acid:

a. No product chemistry deficiencies were previously identified for this active ingredient.

2. The human toxicology submission is ACCEPTABLE.

Regarding the EP:

a. All previously identified deficiencies have been resolved.

Regarding Acetic Acid:

a. All previously identified deficiencies have been resolved.

Regarding Citric Acid:

a. The previously identified deficiency has been resolved.

3. The nontarget toxicology submission is UNACCEPTABLE, but upgradeable pending resolution of the deficiencies listed below.

Regarding Acetic Acid:

a. The request to waive the nontarget insect data requirement has not been granted. The use patterns (flower beds, vegetable gardens, etc.) of the proposed end-use product (EP) are likely to result in exposure to nontarget insects. The nontarget insect data requirement must be satisfied.

Regarding Citric Acid:

a. The request to waive the nontarget insect data requirement has not been granted. The use patterns (flower beds, vegetable gardens, etc.) of the proposed end-use product (EP) are likely to result in exposure to nontarget insects. The nontarget insect data requirement must be satisfied.

NOTE TO RAL:

1. The registrant must provide a statement in the Storage and Disposal section on the label that directs the user not to use bleach to rinse the product container.

2. The registrant must provide clarity regarding the use pattern for the product. It is unclear if the product is intended for commercial and residential use or if it is intended only for commercial use.

STUDY SUMMARIES

Product Chemistry (MRIDs 47330501, 47330505, 47330510-47330512 and 47775901)

Refer to the Data Evaluation Records (DERs).

All previously identified product chemistry deficiencies have been resolved.

Toxicity (MRIDs 47330503, 47330504, 47330507, 47330508 and 47330513-47330518)

The studies submitted to support the proposed EP, SummerSet AllDown Herbicide (EPA File Symbol No. 84069-R) are summarized in Table 1 below.

Table 1.

Study Type/OPPTS Guideline	LD_{50}/LC_{50}/Results	Toxicity Category	MRID
Acute Oral Toxicity/OPPTS 870.1100	> 5,000 mg/kg	IV	47330513
Acute Dermal Toxicity/OPPTS 870.1200	> 5,050 mg/kg	IV	47330514
Acute Inhalation Toxicity/OPPTS 870.1300	> 2.33 mg/L	IV	47330515
Acute Eye Irritation/OPPTS 870.2400	Corrosive	I	47330516
Acute Dermal Irritation/OPPTS 870.2500	Non-irritating	IV	47330517

Skin Sensitization/OPPTS 870.2600	Not a Sensitizer		47330518

Data and information on citric acid and acetic acid were submitted and are adequate. Refer to the DERs for more information.

Non-Targets (MRIDs 47330502, 47330504, 47330506 and 47330508)

Data and information on citric acid and acetic acid were submitted and are adequate for all requirements with the exception of the nontarget insect data requirement. The request to waive the nontarget insect data requirement has not been granted. The use patterns (flower beds, vegetable gardens, etc.) of the proposed end-use product (EP) are likely to result in exposure to nontarget insects.

Justification for Citric Acid as an Active Ingredient (MRID 47330509)

Supplemental information was provided regarding citric acid and phytotoxicity. Based on the information provided, it appears that citric acid can be phytotoxic depending on its concentration. Refer to the DER for more information.

cc: A. L. Gonzales, C. Greene, BPPD Science Review File, IHAD/ARS
A. L. Gonzales, FT, PY-S: 1/21/10

DATA EVALUATION RECORD

ACETIC ACID
(SummerSet All Down Herbicide)

STUDY TYPE: Aquatic Invertebrate Acute Toxicity (OPPTS 850.1010)
Fish Acute Toxicity (OPPTS 850.1075

MRID 47330502

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 08-024

Primary Reviewer:
Eric B. Lewis, M.S.

Signature: _____
Date: _____

Secondary Reviewers:
Sylvia Milanez, Ph.D., D.A.B.T.

Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader

Signature: _____
Date: _____

Quality Assurance:
Lee Ann Wilson, M.A.

Signature: _____
Date: _____

Disclaimer

This review may have been altered subsequent to the contractor's signatures above.

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DATA EVALUATION RECORD

EPA Secondary Reviewer: Angela L. Gonzales 1/21/10 /s/

STUDY TYPE:	Aquatic Invertebrate Acute Toxicity (OPPTS 850.1010) Fish Acute Toxicity (OPPTS 850.1075)
MRID NO:	47330502
DECISION NO:	389083
DP BARCODE:	DP352241
TEST MATERIAL:	Citric acid
PROJECT STUDY NO:	Not provided
SPONSOR:	SummerSet Products, 130 Columbia Court, Chaska, MN 55318
TESTING FACILITY:	Not applicable
TITLE OF REPORT:	OPPTS 850 Series Non-Target Organism, Fate, and Expression for the Citric Acid Starting Material for SummerSet AllDown Herbicide
AUTHORS:	Dawe, D.H., and F.T. Smith
STUDY COMPLETED:	January 14, 2008
CONFIDENTIALITY CLAIMS:	None.
GOOD LABORATORY PRACTICE:	A signed and dated GLP statement was included. The material is not a study and is not subject to 40 CFR Part 160.
CONCLUSION:	The information submitted is sufficient to support the aquatic invertebrate acute toxicity and fish acute toxicity data requirements for the acetic acid component of SummerSet AllDown Herbicide.

Test Material

Acetic acid

Product Description

SummerSet AllDown Herbicide is an end use product for use as a non-selective broadleaf and grass herbicide. The active ingredients (w/w) are 6.0% citric acid and 8.0% acetic acid.

Waiver Request

The registrant is requesting waivers for the following requirements:

Aquatic Invertebrate Acute Toxicity	(OPPTS 850.1010)
Fish Acute Toxicity	(OPPTS 850.1075)

Registrant's Justification

Aquatic Invertebrate Acute Toxicity

In a 24-hr static acute toxicity test with *Daphnia magna*, the 24-hr EC_{50} for acetic acid was 47 mg/L (HPVIS, 2008a). The low EC_{50} value was stated to likely be due to the low pH of the

system (pH not provided). It is unknown if the test material concentration in the test solutions was verified. The test was judged to be valid with restrictions.

In a 48-hr static acute toxicity test with *Daphnia magna*, the 48-hr EC_{50} for acetic acid was 65 mg/L (HPVIS, 2008a). The endpoint was immobilization. The test solutions were apparently not neutralized. It is unknown if the test material concentration in the test solutions was verified. The test was judged to be valid with restrictions.

In a 24-hr static acute toxicity test with *Daphnia magna*, the 24-hr EC_{50} for acetic acid was 6000 mg/L (HPVIS, 2008a). The test occurred in artificial freshwater, and the test solutions were neutralized to pH 8 prior to the exposure. The 24-hr EC_{50} for acetic acid in non-neutralized solutions (pH not stated) was 95 mg/L. The daphnids were not fed during the test. It is unknown if the test material concentration in the test solutions was verified. The test was judged to be valid with restrictions.

Fish Acute Toxicity

In a 96-hr static acute toxicity test with mosquitofish (*Gambusia affinis*), the 96-hr EC_{50} for acetic acid was 251 mg/L (HPVIS, 2008b). The pH ranged from 6.9 to 8.7 during the test. Fish transferred to solutions with acetic acid concentrations between 100 and 1000 ppm swam frantically, but at concentrations of 100 and 180 ppm returned to normal within 24 hrs. At 320 ppm and higher, all fish were dead within 24 hrs. The test was judged to be valid with restrictions.

Reviewer's Comments

The information submitted is adequate to grant the requested waiver for the aceticc acid component of the end use product.

References

HPVIS, 2008a.
http://iaspub.epa.gov/oppthpv/Public_Search.PublicTabs?SECTION=1&epcount=3&v_rs_list=25041760,25041772,25041778

HPVIS, 2008b.
http://iaspub.epa.gov/oppthpv/Public_Search.PublicTabs?SECTION=1&epcount=2&v_rs_list=25041640,25041650

DATA EVALUATION RECORD

ACETIC ACID and CITRIC ACID
(SummerSet AllDown Herbicide and SummerSet AllDown Herbicide Concentrate)

STUDY TYPES: **Acute Oral Toxicity (OPPTS 870.1100)**
Acute Dermal Toxicity (OPPTS 870.1200)
Acute Inhalation Toxicity (OPPTS 870.1300)
Primary Eye Irritation (OPPTS 870.2400)
Primary Dermal Irritation (OPPTS 870.2500)
Bacterial Mutagenicity (OPPTS 870.5265)
Chromosome Aberrations (OPPTS 870.5375)
Dominant Lethal Assay (OPPTS 870.5450)
Sub-Chronic Oral Toxicity-Rats (OPPTS 8700.3100)
Teratology (OPPTS 870.3700)

MRIDs 47330503 and 47330507

Prepared for
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
U.S. Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Prepared by
Toxicology and Hazard Assessment Group
Environmental Sciences Division
Oak Ridge National Laboratory
Oak Ridge, TN 37830
Task Order No. 08-024

Primary Reviewer:
Robin Brothers, Ph.D., D.A.B.T. Signature: _____
Date: _____

Secondary Reviewers:
Sylvia Milanez, Ph.D., D.A.B.T. Signature: _____
Date: _____

Robert H. Ross, M.S., Group Leader Signature: _____
Date: _____

Quality Assurance:
Kimberly G. Slusher, M.S. Signature: _____
Date: _____

Disclaimer

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EPA Secondary Reviewer: Angela L. Gonzales 1/21/10 /s/

STUDY TYPE:	Information to Support: Acute Oral Toxicity (OPPTS 870.1100) Acute Dermal Toxicity (OPPTS 870.1200) Acute Inhalation Toxicity (OPPTS 870.1300) Primary Eye Irritation (OPPTS 870.2400) Primary Dermal Irritation (OPPTS 870.2500) Bacterial Mutagenicity (OPPTS 870.5265) Chromosome Aberrations (OPPTS 870.5375) Dominant Lethal Assay (OPPTS 870.5450) Sub-Chronic Oral Toxicity-Rats (OPPTS 8700.3100) Teratology (OPPTS 870.3700)
MRID NO:	47330503, 47330507
DECISION NO:	389083
DP BARCODE:	DP352241
TEST MATERIAL:	Distilled White Vinegar (a.i., Acetic Acid) Citric Acid (a.i. Citric Acid) In support of SummerSet AllDown Herbicide
PROJECT STUDY NO:	MRID 47330503: none MRID 47330507: none
SPONSOR:	SummerSet products, 130 Columbia Court, Chaska, MN 55318
TESTING FACILITY:	Both documents are compilations of public literature
TITLE OF REPORT:	MRID 47330503: Data Required OPPTS 870 and 880 Series Studies for the Starting Material Acetic Acid in SummerSet AllDown Herbicide MRID 47330507: Data Required OPPTS 870 and 880 Series Studies for the Starting Material Citric Acid in SummerSet AllDown Herbicide
AUTHORS:	MRID 47330503: David H. Dawe and Fredric T. Smith MRID 47330507: David H. Dawe and Fredric T. Smith
STUDY COMPLETED:	MRID 47330503: January 14, 2008 MRID 47330507: January 14, 2008
CONFIDENTIALITY CLAIMS	MRID 47330503: none MRID 47330507: none
GOOD LABORATORY PRACTICE:	MRID 47330503: none MRID 47330507: none
CONCLUSION:	The petitioner has submitted information to support the data requirements for the active ingredients in SummerSet AllDown Herbicide and SummerSet AllDown Herbicide Concentrate for the following studies: Acute Oral Toxicity (OPPTS 870.1100); Acute Dermal Toxicity (OPPTS 870.1200) Acute Inhalation Toxicity (OPPTS 870.1300); Primary Eye Irritation (OPPTS 870.2400); Primary Dermal Irritation (OPPTS 870.2500); Bacterial Mutagenicity (OPPTS 870.5265); Chromosome Aberrations (OPPTS 870.5375); Dominant Lethal Assay (OPPTS 870.5450); Sub-Chronic Oral Toxicity-Rats (OPPTS 8700.3100); and Teratology (OPPTS 870.3700). The data submitted are presentations of publicly available scientific

toxicology data for acetic acid and citric acid, which have historically been available for use in a variety of food and agricultural products. The information presented is sufficient to support the data requirements.

Test Material: Summerset AllDown Herbicide (ready-to-use) (a.i.s 8% acetic acid and 6% citric acid) and SummerSet AllDown Concentrate Herbicide (a.i.s 23% acetic acid and 14% citric acid). The other ingredients include [redacted]

I. TOXICOLOGY DATA SUMMARY:

1. **Methods**: Toxicology data were obtained from the publicly available sources summarized in MRID 47330503 as listed for Acetic Acid in Table 1 and Citric Acid in Table 2.

2. **Results**: The results for determining the toxicological properties of Acetic Acid are shown in Table 1, and for Citric Acid are shown in Table 2.

Deficiencies: None.

TABLE 1 . Tier I Toxicology Data for Acetic Acid[a]				
Guideline Reference No./Property		**Description of Result**	**Toxicity Category**	**Methods/Source**
870.1100	Acute Oral Toxicity	LD_{50} = 3,310 mg/kg (rats) (glacial acetic acid)	III	http://www.inchem.org/documents/jecfa/jecmono/40abcj37.htm
870.1200	Acute Dermal Toxicity	LD_{50}= 1060 mg/kg (glacial acetic acid)	II	Sax's Dangerous Properties of Industrial Materials, 8th ed.
870.1300	Acute Inhalation Toxicity	LC_{50}= 11.4 mg/L-rat (96% acetic acid) LC_{50}= 5620 ppm-mouse	IV	USEPA/HPVIS Robust Summary
870.2400	Primary Eye Irritation	Corrosive	I	Sax's Dangerous Properties of Industrial Materials, 8th ed.
870.2500	Primary Dermal Irritation	4 hour exposure caused corrosion with 60% acetic acid	I	USEPA TSCATS Report for Acetic Acid
870.5265	Bacterial Mutagenicity	Ames Test Negative		USEPA HPV Carboxylic Food Acids 2007
870.5375	Chromosomal Aberrations	In vitro Chinese Hamster Ovary Assay Negative		USEPA HPV Carboxylic Food Acids 2007
870.3100	Sub-Chronic-Rats	**ORAL:** Rats LOAEL = 60 mg/kg-body weight/day (hyperplasia of esopghagus, forestomach) NOAEL not established **INHALATION:** Rats LOAEL= 15 ppm (0.04 mg/L) decreased activity and work capacity NOAEL not established		USEPA HPV Carboxylic Food Acids 2007
870.3700	Teratology	LOAEL maternal and developmental toxicity > 1600 mg/kg-body weight/day NOAEL maternal and developmental toxicity = 1600 mg/kg-body weight/day		USEPA HPV Carboxylic Food Acids 2007

[a]Data from MRID 47330503

TABLE 2. Toxicology Data for Citric Acid[a]				
Guideline Reference No./Property		**Description of Result**	**Toxicity Category**	**Methods/Source**
870.1000	Acute Oral Toxicity	LD_{50} = 11,700 mg/kg	IV	USEPA/HPVIS Robust Summary
870.1200	Acute Dermal Toxicity	500 mg/kg moderate irritation after 24 hours-rabbit	II	Sax's Dangerous Properties of Industrial Materials, 8th ed.
870.2400	Primary Eye Irritation	Rabbit 750 µg -severe irritation after 24 hours (other studies show irreversible damage)	I	Sax's Dangerous Properties of Industrial Materials, 8th ed.
870.2500	Primary Dermal Irritation	Mildly irritating	IV	RTECS 1998
870.5265	Bacterial Mutagenicity	Negative		USEPA HPV
870.5450	Dominant Lethal Assay	No mutagenic potential		USEPA HPV

[a]Data from MRID 47330507